

CLAIMS

WHAT IS CLAIMED IS:

1. A monoclonal anti-idiotype antibody 11D10 produced by hybridoma cell line
5 ATCC No. 12020 or progeny thereof.
2. The antibody of claim 1, further comprising a label capable of producing a detectable signal.
- 10 3. A hybridoma cell line designated ATCC No. 12020 and progeny thereof.
- Sub B1* 4. A purified antibody having identifying characteristics identical to antibody produced by a hybridoma cell line according to claim 3.
- 15 5. A hybridoma having all the identifying characteristics of a cell of the hybridoma cell line according to claim 3.
- 20 6. An isolated polynucleotide comprising a sequence encoding a polypeptide having immunological activity of monoclonal anti-idiotype antibody 11D10, wherein the polypeptide comprises at least 5 contiguous amino acids of a variable region of 11D10.
7. A polynucleotide according to claim 6, wherein the variable region is from a light chain.
- 25 8. A polynucleotide according to claim 6, wherein the variable region is from a heavy chain.

9. The isolated polynucleotide of claim 6, wherein the 5 contiguous amino acids are depicted within SEQ ID NO:2.

10. The isolated polynucleotide of claim 6, wherein the 5 contiguous amino acids
5 are depicted within SEQ ID NO:4.

11 The isolated polynucleotide of claim 6, wherein the encoding sequence is depicted within SEQ ID NO:1.

10 12. The isolated polynucleotide of claim 6, wherein the encoding sequence is depicted within SEQ ID NO:3.

13. An isolated polynucleotide according to claim 6, wherein the polynucleotide encodes at least 5 contiguous amino acids of a complementarity defining region.

15 14. An isolated polynucleotide comprising a region of at least 15 contiguous nucleotides, said region capable of forming a stable duplex with a polynucleotide consisting of light chain variable encoding sequence of SEQ ID NO:1 under conditions where the region does not form a stable hybrid with SEQ ID NO:5 through SEQ ID NO:14.

20 15. An isolated polynucleotide comprising a region of at least 15 contiguous nucleotides, said region capable of forming a stable duplex with a polynucleotide consisting of heavy chain variable encoding sequence of SEQ ID NO:3 under conditions where the region does not form a stable hybrid with SEQ ID NO:15 through SEQ ID NO:32.

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16. A polynucleotide according to claim 6, wherein the polynucleotide is a cloning vector.

17. A polynucleotide according to claim 6, wherein the polynucleotide is an expression vector.
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18. The expression vector of claim 17, wherein the expression vector is vaccinia.

19. A host cell comprising the polynucleotide of claim 6.

10 *S1*
~~SB~~
10 20. A polypeptide having immunological activity of monoclonal anti-idiotype antibody 11D10, wherein the polypeptide comprises at least 5 contiguous amino acids from a variable region of 11D10.

15 21. A polypeptide according to claim 20, wherein the variable region is from a light chain.

20 22. A polypeptide according to claim 20, wherein the variable region is from a heavy chain.

23. The polypeptide of claim 20, wherein the 5 contiguous amino acids are depicted within SEQ ID NO:2.

24. The polypeptide of claim 20, wherein the 5 contiguous amino acids are depicted within SEQ ID NO:4.
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25. The polypeptide of claim 20, wherein the 5 contiguous amino acids are from a complementarity determining region.

Sub
E2

26. The polypeptide of claim 20, wherein the polypeptide contains a region that is homologous to human milk fat globule.

27. A fusion polypeptide comprising the polypeptide of claim 20.

28. The fusion polypeptide of claim 27 further comprising a cytokine.

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Ans E3

29. The fusion polypeptide of claim 28, wherein the cytokine is GM-CSF.

E3
interleukin

30. The fusion polypeptide of claim 28, wherein the cytokine is IL-2.

Sub
E4

15. The fusion polypeptide of claim 27, comprising at least 10 contiguous amino acids of light chain variable region depicted within SEQ ID NO:2 and at least 10 contiguous amino acids of heavy chain variable region depicted within SEQ ID NO:4.

20. The fusion polypeptide of claim 31, wherein the amino acids of SEQ ID NO:2 and the amino acids of SEQ ID NO:4 are joined by a linker polypeptide of about 5 to 20 amino acids.

WCG
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33. The fusion polypeptide of claim 27, comprising the light chain variable region and the heavy chain variable region of monoclonal antibody 11D10.

34. The fusion polypeptide of claim 27 further comprising a heterologous immunoglobulin constant region.

Sub E 35. A humanized antibody comprising the polypeptide of claim 20.

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36. A polymeric 11D10 polypeptide comprising a plurality of the polypeptide of claim 20.

Sub BY 10 37. A pharmaceutical composition comprising an effective amount of monoclonal anti-idiotype antibody 11D10 of claim 1 and a pharmaceutically acceptable excipient.

Sub BY 10 38. A pharmaceutical composition comprising an effective amount of the polynucleotide of claim 6 and a pharmaceutically acceptable excipient.

15 39. A pharmaceutical composition comprising an effective amount of the polypeptide of claim 20 and a pharmaceutically acceptable excipient.

Sub BY 20 40. A vaccine comprising an effective amount of monoclonal anti-idiotype antibody 11D10 of claim 1 and a pharmaceutically acceptable excipient.

41. A vaccine comprising an effective amount of the polynucleotide of claim 6 and a pharmaceutically acceptable excipient.

Sub BY 25 42. A vaccine comprising an effective amount of the polypeptide of claim 20 and a pharmaceutically acceptable excipient.

43. The vaccine of claim 37, further comprising an adjuvant.

Sub C
44. The vaccine of claim 38, wherein the vaccine is a live virus or viral expression vector.

5 45. The vaccine of claim 44, wherein the vaccine is vaccinia.

46. A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of monoclonal anti-idiotype antibody 11D10 of claim 1 to the individual.

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47. A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of the vaccine of claim 43 to the individual.

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48. The method of claim 46, wherein the advanced human milk fat globule associated disease is breast cancer.

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49. A method for removing a labeled anti-human milk fat globule (HMFG) antibody from an individual who has received a labeled anti-HMFG antibody, comprising administering monoclonal antibody 11D10 of claim 1 to the individual.

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50. A method for detecting the presence of an anti-human milk fat globule (HMFG) antibody bound to a tumor cell comprising the steps of contacting the tumor cell with monoclonal antibody 11D10 of claim 1 for a sufficient time to allow binding to the anti-HMFG antibody, and detecting the presence of any 11D10 which is bound to the anti-HMFG antibody.

51. A method for detecting an anti-human milk fat globule immunological response in an individual comprising the steps of (a) contacting a biological sample from the individual with the monoclonal antibody 11D10 of claim 1 under conditions that permit formation of a stable complex between monoclonal antibody 11D10 and an antibody that binds to 11D10; and (b) detecting any stable complexes formed.

52. A method of detecting in a sample an antibody that binds to monoclonal antibody 11D10 comprising the steps of: (a) contacting antibody from a sample obtained from the individual with the polypeptide of claim 20 under conditions that permit the formation of a stable antigen-antibody complex; and (b) detecting the stable complex formed in step (a), if any.

53. A method of palliating human milk fat globule associated disease in an individual having advanced human milk fat globule associated disease comprising administering an effective amount of monoclonal antibody 11D10 of claim 1 to the individual.

54. A kit for detection or quantitation of an anti-human-milk-fat-globule antibody comprising monoclonal anti-idiotype antibody 11D10 of claim 1 in suitable packaging.

55. The kit of claim 54, wherein the 11D10 comprises a detectable label.

56. A kit for detection or quantitation of an anti-human milk fat globule antibody in a biological sample comprising the 11D10 polypeptide of claim 20 in suitable packaging.

57. A kit for detection or quantitation of a polynucleotide comprising a polynucleotide encoding a variable region of monoclonal antibody 11D10 or a portion thereof, said kit comprising the polynucleotide of claim 14 in suitable packaging.

5 58. A kit for detection or quantitation of a polynucleotide comprising a polynucleotide encoding a variable region of monoclonal antibody 11D10 or a portion thereof, said kit comprising the polynucleotide of claim 15 in suitable packaging.

DRAWING NO. 121395

10 add C27
X
E 7
15 add F6
20 add G3

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